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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,892

10/23/2006

Jean-Noel Thorel

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ALEXANDRIA, VA 22320-4850

EXAMINER

MILLIGAN, ADAM C

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

02/22/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/583,892	<b>Applicant(s)</b> THOREL ET AL.	
	<b>Examiner</b> ADAM MILLIGAN	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21,24-32 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) 32 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,24-31 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1 pg (10/23/2006)</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/23/2009 has been entered.

Applicants' arguments, filed 12/23/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Information Disclosure Sheet***

Reference FR 2 609 397 cited on the IDS dated 10/23/2006 has been considered as requested. An annotated IDS indicating consideration is attached showing all references submitted have now been considered.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 21, 36 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub (U.S. 2002/0019431) in view of Thorel (FR 2 831 059)

First, Applicants' assert that in light of the amendment to claim 21, it would not have been obvious to select the specific combination of polyols instantly recited. Second, Applicants' argue that Straub does not disclose that a combination of sugars should be provided to the matrix in combination. Third, Applicants' argue that it would not have been obvious to combine Straub and Farmer because the two references are unrelated. Fourth, Applicants argue that unexpected results have been demonstrated because the claimed galenic base showed increased cell viability and reduced skin irritation when compared to a prior art composition.

Examiner disagrees. With regard to Applicants' first and third arguments, a new ground of rejection is asserted below which overcomes these arguments. Specifically, Thorel (FR 2 831 059) has replaced Farmer (WO 98/47374) as a secondary reference.

With regard to Applicants second argument, Straub discloses a list of sugars which may be used in the invention. The reference in no way indicates that only one sugar should be used. On the contrary, Straub states that "The porous drug matrices may include *one or more* tonicity agents, *such as* salts or *sugars* to adjust a hypotonic solution of a drug to isotonic so that the drug, when in solution, is physiologically compatible with the cells of the body tissue of the patient." (Straub - ¶ 33). It is further noted that the section that applicants cite in support of their position states that the matrix "may contain hydrophilic excipients such as water soluble *polymers or sugars*" which when written in the plural would suggest multiples can be used.

Fourth, the results obtained do not appear to be unexpected. The test performed compares a base having no sugars and a base having sugars. As mentioned above, sugars are known to adjust a hypotonic solution to isotonic (Straub - ¶ 33). One of ordinary skill in the art would recognize that an isotonic solution would keep the tonicity of the skin steady, thus minimizing irritation.

As previously mentioned, the primary reference does not teach the incorporation of fructoolosacharides into the drug matrix.

Thorel is now cited for the teaching that a topical composition which includes fructoolosacharides and a physiologically acceptable medium for treating greasy skin and acne (Derwent Acc No. 2003-544019). Thorel teaches that fructoolosacharides help to treat the greasy skin and acne (Thorel- p.3, lines 5-12).

Thorel does not teach the addition of xylitol, mannitol, and rhamnase

It would be obvious to one of ordinary skill in the art to modify the matrix of the primary reference by adding fructoolosacharides in order incorporate the additional benefit of treating greasy skin and acne as taught by the secondary reference.

**Claims 24, 37 and 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub (U.S. 2002/0019431) in view of Thorel (FR 2 831 059), the combination further in view of Carson (U.S. 6,391,324) and Knight (U.S. 6,017,549).

First, Applicants point out that claims 24, 37 and 38 depend from claim 21 and additional references do not cure the deficiencies with regard to claim 21.

Second, Applicants' argue that because pulegone is taught to enhance the uptake of endogenous glucose, there would not have been any rationale to modify the matrix taught by Straub to include glucose because the matrix does not contain pulegone and the uptake of endogenous glucose is not desired.

Third, Applicants' argue that the ordinarily skill artisan would not have had any reason to substitute an emulsifier of Knight for the emulsifier disclosed by Straub for forming the dry porous matrix of Straub because the dry porous matrix is not topically applied to skin before being reconstituted into, for example, a cream or ointment.

Examiner disagrees. First, claim 21 is discussed above and shown to be properly rejected.

Second, Carson is cited for the teaching that glucose glutamate may be incorporated into a cosmetic skin care composition. The fact that Straub teaches a benefit is achieved by including glucose glutamate in combination with pulegone does not negate the rejection as applicant asserts, given the component alone may be included into the composition. Further, pulegone may be included in the instantly claimed base if the benefit disclosed in Straub is desired, given claim 21 uses the transition phrase "contains", which is interpreted to be an open, allowing additional components while still requiring the specifically recited polyols.

Third, it is unclear how further processing of the emulsifier prior to topical administration would negate the added benefit of the emulsifier taught by Knight. Where the presence of cetearyl glucoside in a topical formulation is taught by the prior art to enhance the barrier function (Knight at col. 2, lines 27-43), it follows that the presence of

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that same substance in another topical formulation would also be expected to enhance the barrier function. It is noted that Applicants' have not provided any data contrary to this expectation. Thus, it is submitted that the added benefit of reduced skin irritation would be achieved by substituting the cetearyl glucoside emulsifier of Knight for the emulsifier taught by Straub.

**Claims 25 and 27-31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub (U.S. 2002/0019431) in view of Thorel (FR 2 831 059), the combination further in view of Kryzysik (U.S. 6,440,437).

First, Applicants point out that claims 25 and 27-31 depend from claim 21 and additional references do not cure the deficiencies with regard to claim 21.

Second, Applicants argue that Krysik is nonanalogous art because it is directed to a skin health enhancing wet wipe, which is not related to increasing cell viability or reducing skin irritation.

Examiner disagrees. In regard to Applicants' first argument, claim 21 is discussed above and is properly rejected.

Second, the wet wipes described by Krysik contain a liquid (Col. 14, lines 21-33) and an active agent (col. 13, lines 49-67). The liquid thus serves as a base for carrying the active. Further, the wipes formulation of the wet wipes enhances the skin barrier against irritants (col. 18, lines 25-36). Where the purpose of the wipes is shown to reduce irritation, the tertiary reference is analogous to the primary and secondary references, given their common application and combined benefits.

**Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Straub (U.S. 2002/0019431) in view of Thorel (FR 2 831 059), the combination further in view of Mekideche (JP 2001-48776).

Applicants' point out that claims 25 and 27-31 depend from claim 21 and additional references do not cure the deficiencies with regard to claim 21.

Examiner disagrees. Claim 21 is discussed above and is properly rejected.

### ***Conclusion***

No claims allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612

/A. M./  
Examiner, Art Unit 1612